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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176

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EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 21-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and response, both filed on 1 July 2009.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 14, 15, 16, and 18 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,162,177 ("Stupak").

Stupak discloses a solid dosage form (*see* col. 1, lines 6-10) comprising:

- the chewable tableted center, wherein the chewable tableted center is not a chewing gum of instant claims 8 and 16 (*see* col. 2, lines 16-49 for description of center and col. 3, lines 15-30 for description of tableting process);
- the coating comprising a medicament, wherein said coating surrounds the center, the coating comprising at least 50% by weight of the product (*see* example 1); and
- the compressible excipients of instant claims 14 and 18 (*see* col. 2, lines 16-49).

The coating disclosed by Stupak does not have a shellac layer, thus meeting the limitation of instant claim 15.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 8, 10-13, 16, 19, and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,162,177 ("Stupak") in view of U.S. Patent No. 6,060,078 ("Lee").

Stupak is discussed above.

Stupak differs from the instant application in that it does not disclose the claimed taste masking agents.

Lee teaches a chewable tablet (*see* col. 1, lines 6-12) comprising:

- the outer layer taste masking agent (*e.g.* dextrose and aspartame) of instant claims 10 and 19 (*see* col. 2, line 46);
- the dextrose of instant claim 11 (*see* col. 2, line 46); and
- the aspartame of instant claims 13 and 20.

While Lee does not explicitly teach the percentages of instant claims 12, 13, 19, and 20, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

Lee explains that sugars such as dextrose and aspartame may comprise 50-90 weight % by total weight of the ingredients (*see* col. 2, lines 47-48). Furthermore, in example 1, aspartame comprises 0.5% of the formulation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a taste masking agent to the coating of a chewable pharmaceutical formulation, as taught by Stupak in view of Lee. One of ordinary skill in the art at the time the invention was made would have been motivated to add a taste masking agent because it makes the chewable formulation more palatable to the consumer.

*

2. Claims 8, 9, 16, and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,162,177 ("Stupak") in view of U.S. Patent No. 5,126,151 ("Bodor").

Stupak is discussed above.

Stupak explains that adding a medicament to the coating results in immediate release of the medicament (*see* col. 1, line 56).

Stupak differs from the instant application in that it does not disclose the medicaments of instant claims 9 and 17. However, Bodor teaches a coating composition of an oral dosage form (*see* col. 10, line 6) comprising, *e.g.*, antihistamines (*see* col. 10, line 32).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a medicament such as an antihistamine to the coating of an oral dosage form, as taught by Stupak in view of Bodor. One of ordinary skill in the art at the time the invention was made would have been motivated to add a medicament to the coating because it results in immediate release of the medicament, as explained by Stupak (*see* above).

* * * * *

Response to Arguments

Applicants' arguments filed on 1 July 2009 have been fully considered but they are not persuasive.

Applicants argue that because of the composition of the core, the existence of an enteric coating, and the teachings of intended use of the dosage forms in Stupak, Stupak fails to disclose or suggest a product with a chewable tableted center. See remarks, page 9.

Examiner respectfully submits that the Stupak reference reads on the instant application in view of the current claim language and the language of the disclosure.

Regarding intended use of the Stupak formulation and the use of an enteric coating, the difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991)."

Regarding the composition of the enteric coating, the instant specification explains that the claimed formulation may be chewed or crunched (see specification, page 9, line 21). Either chewing or crunching will result in the medicament or agent in the saliva to be forced through the oral mucosa in the buccal cavity due to the pressure created while chewed. As such, examiner respectfully submits that the Stupak invention directly reads on the instant claims in view of the broad interpretation of "chewed" in the specification as either chewing or crunching.

Applicants argue that Lee teaches away from Stupak because Lee is prepared at room temperature while Stupak teaches a melted combination of medicament and additives. See remarks, page 10.

Applicants rationalize the teaching away argument by pointing out differences in the method of making the core of Stupak and the medicament containing core of Lee. However, Lee was invoked only for the teaching of outer layer taste masking agents.

As such, the method of making the core in Stupak and Lee does not affect the teaching for which Lee was cited.

Applicants argue that Stupak does not teach a coating comprising a medicament. See remarks, page 10.

Examiner respectfully disagrees. Stupak teaches a coating comprising a medicament at, e.g., Example. 1.

Applicants argue that there is no reason to combine Stupak and Bodor. See remarks, page 10.

As explained above, Stupak teaches a coating comprising a medicament. Bodor was invoked for the limited teaching of particular agents contained in the coating as claimed instantly. Bodor, like Stupak, is a consumable product comprising a core and a coating (see, e.g., abstract, col. 10, line 6). As such, examiner respectfully submits that Stupak and Bodor may be properly combined.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615